Commercial PA Criteria

Effective: January 1, 2019

Prior Authorization: Actemra

Products Affected: Actemra (tocilizumab) subcutaneous solution

Medication Description: Tocilizumab is an interleukin-6 (IL-6) receptor inhibitor that binds specifically to both the soluble and membrane-bound IL-6 receptors and has been shown to inhibit IL-6 mediated signaling via these receptors. IL-6 is produced by a variety of cell types including synovial and endothelial cells leading to local production of IL-6 in joints affected by inflammatory processes such as rheumatoid arthritis.

Covered Uses:

1. **Giant cell arteritis** in adults.
2. **Interstitial lung disease associated with systemic sclerosis,** to slow the rate of decline in pulmonary function in adults.
3. **Polyarticular juvenile idiopathic arthritis**, for the treatment of active disease in patients ≥ 2 years of age.
4. **Rheumatoid arthritis**, for treatment of adults with moderate to severe active disease who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs).
5. **Systemic juvenile idiopathic arthritis**, for the treatment of active disease in patients ≥ 2 years of age.

Exclusion Criteria:

1. Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).
2. COVID-19 - Forward all requests to the Medical Director. Only Actemra intravenous is indicated for treatment of COVID-19 in hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.
   Note: This includes requests for cytokine release syndrome associated with COVID-19
3. Crohn's Disease

Required Medical Information:

1. Diagnosis
2. Previous medications tried and failed

Age Restrictions:

1. Juvenile idiopathic arthritis and Cytokine Release Syndrome (CRS) : 2 years of age and older
2. Rheumatoid arthritis and Giant cell arteritis: 18 years of age and older

Prescriber Restrictions: Must be prescribed by, or in consultation with, a rheumatologist.

Coverage Duration:

Initial: 6 months

Continuation: 1 year

Other Criteria:

1. **Giant Cell Arteritis.**
   Initial Therapy: Approve if the patient meets the following criteria
   A. Patient has tried one systemic corticosteroid; **AND**
      Note: An example of a systemic corticosteroid is prednisone.
   B. The medication is prescribed by or in consultation with a rheumatologist

2. **Interstitial Lung Disease Associated with Systemic Sclerosis**
   Initial Therapy. Approve if the patient meets ALL of the following criteria (A, B, C, D **AND** E):
   A. Patient is ≥ 18 years of age; AND
   B. Patient has elevated acute phase reactants, defined as at least ONE of the following criteria (I, ii, **OR** iii):
      i. C-reactive protein (CRP) ≥ 6 mg/mL **OR**
      ii. Erythrocyte sedimentation rate (ESR) ≥ 28 mm/h; **OR**
      iii. Platelet count ≥ 330 x 109/L; **AND**
   C. Forced vital capacity (FVC) is > 55% of the predicted value; **AND**
   D. Diagnosis is confirmed by high-resolution computed tomography; **AND**
   E. The medication is prescribed by or in consultation with a pulmonologist or a rheumatologist.

3. **Polyarticular Juvenile Idiopathic Arthritis**
   Initial Therapy: Approve if the patient meets the following criteria (A **AND** B)
   A. Patient meets ONE of the following criteria (i, ii, iii, **OR** iv):
      i. Patient has tried one other systemic therapy for this condition; **OR**
         Note: Examples of other systemic therapies include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of one biologic other than the requested drug also counts as a trial of one systemic therapy for Juvenile Idiopathic Arthritis. A biosimilar of Actemra does not count.
      ii. Patient will be starting on Actemra subcutaneous concurrently with methotrexate, sulfasalazine, or leflunomide; **OR**
      iii. Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; OR
         Note: Examples of absolute contraindications to methotrexate include pregnancy, breastfeeding, alcoholic liver disease, immunodeficiency syndrome, and blood dyscrasias; OR
      iv. Patient has aggressive disease, as determined by the prescriber; **AND**
   B. Patient meets ONE of the following (i **OR** ii):
      i. Patient has a documented failure of, or intolerance to an adalimumab product; **OR**
         Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of Cimzia, Enbrel, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts

ii. According to the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder.

4. **Rheumatoid Arthritis**

Initial Therapy: Approve if the patient meets the following criteria (A **AND** B)

A. Patient has tried one conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; **AND**

Note: Examples of conventional DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial with at least one biologic other than Actemra. A biosimilar of Actemra does not count. A patient who has already tried a biologic for rheumatoid arthritis is not required to "step back" and try a conventional synthetic DMARD.

B. Patient meets ONE of the following (i **OR** ii):

i. Patient has a documented failure of, or intolerance to an adalimumab product; **OR**

Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of Cimzia, Enbrel, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts

ii. According to the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder.

5. **Systemic Juvenile Idiopathic Arthritis**

Initial Therapy: Approve if the patient meets the following criteria (A **AND** B)

A. Patient has tried one other systemic therapy for this condition; AND

Note: Examples of other systemic therapies include a corticosteroid (oral, intravenous), a conventional synthetic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine], or a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of one biologic other than Actemra (e.g., Kineret [anakinra subcutaneous injection], a tumor necrosis factor inhibitor [e.g., an etanercept product, an adalimumab product, an infliximab product], or Ilaris [canakinumab subcutaneous injection]) also counts towards a trial of one other systemic therapy for systemic juvenile idiopathic arthritis. A biosimilar of Actemra does not count.

B. Patient meets ONE of the following (i **OR** ii):

iii. Patient has a documented failure of, or intolerance to an adalimumab product; **OR**

Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of Cimzia, Enbrel, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts

iv. According to the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder.

Continuation:

A. Patient meets all initial authorization criteria, **AND**

B. Patient has been established on therapy for at least 6 months, **AND**
C. Patient achieves or maintains a positive clinical response after at least 6 months of therapy with Actemra SC as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References:

1. Actemra® [prescribing information]. South San Francisco, CA: Genentech; December 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019
2	Update	Clarification to include systemic JIA as a covered indication	Covered Uses Age Restriction Coverage Duration Other Criteria	2/27/2020
4	Update	Added criteria to require the use of Humira prior to Actemra SQ for RA, separated Polyarticular Juvenile Idiopathic Artheritis from Systemic JIA. Removed Humira trial for systemic Juvenile Idiopathic Arthritis. Added exclusion criteria:Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs). Added Cytokine Release Syndrome to covered uses, age restrictions, and other criteria Removed: "Patient meets all initial authorization criteria" from continuation criteria	All	1/1/2021
5	Update	Updated "Humira" to "Adalimuab" in Other Criteria	Other Criteria	05/11/2023
6	Update	Addition of Interstitial lung disease associated with systemic sclerosis with criteria to label. Removal of cytokine release syndrome Removed current criteria for RA/PJIA/SJIA/Giant Cell Arteritis and replaced with Select criteria to label Removed Dosage Limitations Addition tp PJIA/RA/SJIA - Patient meets ONE of the following (i **OR** ii):Patient has a documented failure of, or intolerance to an adalimumab product; **OR** According to the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder.	Covered uses Other Criteria Exclusion criteria	12/18/2023